

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

Gunter Schmidt et al..

Application No. 09/806,564

Filed: July 19, 2001

Title: Characterising Polypeptides Through Cleavage and Mass Spectrometry

Group Art Unit: 1627

Examiner: L. Guo

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TECH CENTER 1600/2900

\* \* \* \* \*

ELECTION AND AMENDMENT

Hon. Commissioner of Patents  
Washington, D.C. 20231

Sir:

Prior to substantive examination, kindly cancel claims ~~14-17~~ and substitute the following claims therefore:

--18. The method of claim 13, wherein the cleavage agent at least one compound selected from the group consisting of a Lys-C endopeptidase, a thiocyanate compound, cyanogen bromide, BNPS-skatole, trypsin, chymotrypsin and/or thrombin.

al 19. The method of any one of claims 3-13 and 18 and the capping agent is at least one compound selected from the group consisting of an iodacetate compound, an isocyanate compound, a silyl compound, an anhydride, a vinylsulphone compound and a vinyl pyridine derivative.

20. The method of any one of claims 3-13 and 18 which further characterizing the one or more polypeptides in the sample by comparison with a database.

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01 FC:2202 36.00 CH  
02 FC:2201 210.00 CH

21. A method for detecting the expression of one or more proteins in a tissues, which method comprises characterizing a peptide of polypeptides comprising the following steps:

- (a) contacting a sample comprising one or more polypeptides with a first cleavage agent to generate polypeptide fragments;
- (b) isolating one or more polypeptide fragments, each fragment comprising the N-terminus or the C-terminus of the polypeptide from which it was fragmented;
- (c) identifying the isolated fragments by mass spectrometry;
- (d) repeating steps (a)-(c) on the sample using a second cleavage agent that cleaves at a different site from the first cleavage agent; and
- (e) characterizing the one or more polypeptides in the sample from the fragments identified in steps (c) and (d).

22. The method of claim 21 which further comprise characterizing the population of polypeptides by comparison with a database.

23. A method for assaying for one or more specific polypeptides in a sample, which method comprises characterizing a population of polypeptides comprising the following steps:

- (a) contacting a sample comprising one or more polypeptides with a first cleavage agent to generate polypeptide fragments;
- (b) isolating one or more polypeptide fragments, each fragment comprising the N-terminus or the C-terminus of the polypeptide from which it was fragmented;
- (c) identifying the isolated fragments by mass spectrometry;

(d) repeating steps (a)-(c) on the sample using a second cleavage agent that cleaves at a different site from the first cleavage agent;

(e) characterizing the one or more polypeptides in the sample from the fragments identified in steps (c) and (d); and

(f) determining the presence or absence of said one or more specific polypeptides based on the presence or absence of one or more specific fragments corresponding to said polypeptides.

24. The method of claim 23, which further comprises characterizing said population of polypeptides by determining the presence or absence of said one or more specific polypeptides by comparison to a database.--

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In respect to the Restriction Requirement, Applicants elect with traverse, Group I, claims 1-13 and 18-20 (based on the cancellation of claims 14-15 in favor of claims 18-19, and the introduction of new claim 20, dependent on claims 3-13 and 18.

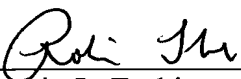
The traversal is on the basis that the two groups involve very related methods which would be anticipated to have substantially overlapping searches. The relatedness of the groups is emphasized by the cancellation of claims 16 and 17 in favor of new claims 21-23, which positively recite the steps of claim 1. Essentially, the first group of claims (1-13 and 16-18) refers to a method of identifying a polypeptide by determining the identity of fragment peptides and using the peptide identity to determine the polypeptide identity. The second group of claims (21-23) refers to the determination of an expression profile. The determination of an expression profile requires use of the method of claims 1 to 13 and 16-18 for sequencing a peptide and subsequent comparison with known data (such a list or database of expected proteins) to determine which proteins are present and which are absent. As such,

both methods are very similar, and the expression profiling method only differs from the method of claim 1 in that the sample is taken from a cell and that the population of polypeptides including the polypeptides present in the cell sample. Accordingly, both groups of claims clearly relate to the same invention.

Therefore, based on the foregoing all of the claims should be examined together. Support for the added claims is in the description at pages 18 and 19 which refers to determining the uniqueness of protein identifications by comparison to a database.

It is believed that this is a complete response to the outstanding Restriction Requirement.

If the examiner has any questions in connection with this election, he is kindly requested to contact the undersigned at the telephone number given below, so that prosecution may be expedited.

By:   
Robin L. Teskin  
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Date: November 1 2002

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Inventor(s): Gunter Schmidt et al.  
 Appln. No.: 09/ 806,564  
 Series Code ↑ Serial No. ↑

Filed: July 19, 2001

Hon. Commissioner of Patents  
 Washington, D.C. 20231

Sir:

**REPLY/AMENDMENT/LETTER**

Date: November 1, 2002

This is a reply/amendment/letter in the above-identified application and includes the herewith attachment of same date and subject which is incorporated hereinto by reference and the signature below is treated as the signature to the attachment in absence of a signature thereto.

**FEE REQUIREMENTS FOR CLAIMS AS AMENDED**

1. Small Entity claim A. <input type="checkbox"/> NOT made B. <input type="checkbox"/> Withdrawn C. <input type="checkbox"/> made herewith D. <input checked="" type="checkbox"/> made previously		For B & C See <b>Required</b> <b>Separate</b> Paper (Pat-256)		Claims remaining after amendment	Highest number previously paid for	Present Extra	Large/Small Entity	Additional Fee	Fee Code Lg/Sm	
2. Total Effective Claims				24	**minus	20	4	x \$18/\$9 =	+ \$36	103/203
3. Independent Claims				8	***minus	3	5	x \$84/\$42 =	+ \$210	102/202
4. If amendment enters proper multiple dependent claim(s) into this application for first time (leave blank if this is a reissue application)..... add								+ \$280/\$140 =	+ \$0	104/204
5. Original due Date: November 2, 2002				<input type="checkbox"/> NONE						
6. Petition is hereby made to extend the original due date to cover the date this response is filed for which the requisite fee is attached				(1 mo)	\$110/\$55 =					115/215
				(2 mos)	\$400/\$200 =					116/216
				(3 mos)	\$920/\$460 =					117/217
				(4 mos)	\$1,440/\$720 =					118/218
				(5 mos)	\$1,960/\$980 =					128/228
7. Enter any previous extension fee paid since above original due date and subtract							- \$0			
8.							Extension Fee	+ \$0		
9. If Terminal Disclaimer attached, add Rule 20(d) official fee .....							+ \$110/\$55	+ \$0		148/248
10. If IDS attached requires Official Fee under Rule 97 (c), .....							+ \$180	+ \$0		126
or if Rule 97(d) Request .....							+ \$180			126
11. After-Final Request Fee per rules 129(a) and 17(r) .....							+ \$740/370	+ \$0		146/246
12. No. of additional inventions for examination per Rule 129(b).....							x \$740/370 ea	+ \$0		149/249
13. Request for Continued Examination (RCE) .....							+ \$740/370	+ \$0		1179/1279
14. Petition fee for .....								+ \$0		
15.							<b>TOTAL FEE =</b>	<b>\$246</b>		
16. *If the entry in this space is less than entry in next space, the "Present Extra" result is "0".										
17. **If the "Highest number previously paid for" in this space is less than 20, write "20" in this space.										
18. ***If the "Highest number previously paid for" in this space is less than 3, write "3" in this space.										

Our Deposit Account No. 03-3975)

(Our Order No. 068800 0279469

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**CHARGE STATEMENT:** The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficiencies only) now or hereafter relative to this application and the resulting Official Document under Rule 20, or credit any overpayment, to our Accounting/Order Nos. shown above, for which purpose a duplicate copy of this sheet is attached.

This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal sheet is filed.

Query: Is appeal deadline now? If so, file Notice of Appeals separately.

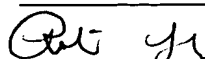
Pillsbury Winthrop LLP  
 Intellectual Property Group

By Atty: Robin L. Teskin

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**NOTE: File this cover sheet in duplicate with PTO receipt (PAT-103A) and attachments**